IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

CW, et al.,	)	
	)	
Plaintiffs,	)	
v.	)	CASE NO. 3:10-cv-00087-PPS-CAN
	)	
TEXTRON, INC.,	)	
	)	
Defendant.	)	

REPLY BRIEF IN SUPPORT OF DEFENDANT'S MOTION IN LIMINE TO EXCLUDE THE REPORT AND TESTIMONY OF PLAINTIFFS' EXPERT WITNESS, JILL E. RYER-POWDER, PH.D.

I. Introduction

Jill E. Ryer-Powder, Ph.D., has issued an expert report in which she opines that the levels and duration of plaintiffs' exposure to vinyl chloride were capable of causing the medical problems they allegedly suffered while living in Rochester, as well as an unacceptably high risk of cancer in the future. Textron, Inc. has moved to exclude Dr. Ryer-Powder's report and testimony for three reasons. First, her comparison of levels of vinyl chloride allegedly present in this case to regulatory standards for that chemical is a methodology courts have uniformly held deficient to establish general causation. Second, the studies Dr. Ryer-Powder cited to show the adverse health effects vinyl chloride can cause all involved levels of exposure thousands of times higher than here, and in many instances involved subjects other than humans, with no scientific justification offered by the authors of those studies or by Dr. Ryer-Powder for extrapolating the studies' results to the facts of this case. And third, Dr. Ryer-Powder's dosage calculations greatly overstated plaintiffs' exposure to vinyl chloride due to her failure to account for the effects of the water-filtration system that was present in their home.

Plaintiffs respond that any criticism of Dr. Ryer-Powder's comparisons of plaintiffs' levels of exposure to regulatory standards goes to the weight of her opinions and not to their admissibility. And they claim that Textron's own experts conceded that comparison to regulatory standards does provide evidence of causation. Plaintiffs also claim that the studies cited by Dr. Ryer-Powder involved levels of exposure comparable to plaintiffs', and that in any event Dr. Ryer-Powder has now explained the basis for extrapolating those studies' results to this case. Finally, plaintiffs claim that because Dr. Ryer-Powder based her calculations and opinions on the concentration of vinyl chloride found in a sample of water that had passed through the home's filtration system, she did not fail to account for the effects of that system.

Plaintiffs' response to Textron's motion to exclude Dr. Ryer-Powder's opinions blatantly and repeatedly misstates both the facts and the law. Contrary to plaintiffs' claim, no case has ever held that criticism of an expert's comparison of levels of exposure to regulatory standards goes to the weight of the expert's general-causation opinion rather than to its admissibility. And Textron's experts did not say that such comparisons provide evidence of causation; they said exactly the opposite. And while plaintiffs claim that a particular study cited by Dr. Ryer-Powder showed that exposure to vinyl chloride at a level only ten times greater than here caused an increased rate of cancer in rats, the study itself reveals that a statistically significant correlation between tumor rate and vinyl chloride exposure in fact began at a level *5,500* times higher than the dose plaintiffs allegedly received. And finally, uncontradicted evidence shows that the vinyl chloride level used by Dr. Ryer-Powder in her dosage calculations and opinions was based on a sample taken from an outside spigot at plaintiffs' home that had not passed through the home's filtration system.

Therefore, because Dr. Ryer-Powder's opinions do not meet the reliability requirements of Federal Rule of Evidence 702, her expert report and testimony should be excluded.

II. Argument.

A. Exceedance of Regulatory Standards Does Not Provide Evidence of Causation.

According to plaintiffs, "The comparison to a regulatory level can be used as a basis to establish causation, so any criticism goes to the weight of the evidence, and not to an expert's admissibility. The cases cited by Textron confirm the distinction between weight versus admissibility." (Plaintiffs' Brief at 6.) That is utterly false. What the cases that Textron cited in its initial brief actually show is that a plaintiff's exposure to a chemical at a level above some regulatory standard *cannot* provide evidence that the chemical caused or was capable of causing the plaintiff's illness, and that a medical expert's causation opinion that is based on exceedance of such standards is *inadmissible*. *See Cunningham v. Masterwear Corp.*, 569 F.3d 673, 674-75 (7th Cir. 2009) (affirming exclusion of medical expert's causation opinion because it was based on exceedance of "what the Indiana environmental agency considers the safe level of exposure to the chemical."); *Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 195, 198 (5th Cir. 1996) (observing that regulatory agencies' thresholds of proof of correlation between exposure and illness are lower than that used in tort law, and affirming exclusion of medical expert's causation opinions that were founded on agency standards); *Baker v. Chevron USA, Inc.*, 680 F. Supp. 2d 865, 880 (S.D. Ohio 2010) ("Initially, the Court notes that to the extent that Dr. Dahlgren relies on the fact that Plaintiffs' illnesses were caused because they were exposed to benzene in excess of regulatory levels, his opinions are not admissible."). Not one word in the cases cited by Textron suggests that an expert's reliance on exceedance of regulatory standards

as grounds for an opinion on general causation affects only the weight to be given the opinion and not its admissibility. And plaintiffs themselves have cited no cases that suggest that, either.

Plaintiffs also maintain that "[c]ontrary to the arguments in its Brief, Textron's experts [Drs. McHugh and Phillips] testified that comparison to regulatory standards *does* provide evidence of causation." (Plaintiffs' Brief at 4; emphasis in original.) Plaintiffs apparently make this argument on the theory that witnesses' testimony can somehow supplant the precedents just described, all of which hold that comparisons to regulatory standards cannot provide evidence of causation and do not provide satisfactory grounds for a medical expert's causation opinion. But besides the obvious fact that testimony cannot nullify legal precedents, neither Dr. McHugh nor Dr. Phillips testified as plaintiffs claim.

What Dr. McHugh actually said, in the very passage of deposition testimony cited by plaintiffs, is that because regulatory standards are deliberately set far below the levels at which any adverse health effects have been observed, it follows that if a person's exposure is at or below those standards it may safely be concluded that exposure to that chemical is *not* a possible cause of that person's medical problems. In Dr. McHugh's June 14, 2012 expert report (Exhibit F to Textron's initial brief), he reaffirmed that very point—that exceedance of regulatory standards *cannot* be used to show causation, and that doing so is scientifically invalid:

> [T]he regulatory concentrations and no effect levels are established based on very conservative assumptions in order to provide a high level of protection to potentially exposed populations. Use of these regulatory values to evaluate the potential non-cancer health effects or cancer risk for individuals is inappropriate, scientifically invalid, and a direct contradiction of agency recommendations (e.g., ATSDR, 2005).

(McHugh Report at 10.)

Dr. Phillips likewise did not testify that comparison to regulatory standards provides evidence of causation. His expert report listed 12 different regulatory standards for exposure to

contaminants, simply as background for his discussion of health effects of chemicals. One of those standards was OSHA's Permissible Exposure Limits, or "PELs." At his deposition Dr. Phillips was asked, "How is a PEL applicable to [C.W.'s] and [E.W.'s] exposure to vinyl chloride?" He responded, "It's not directly applicable. It just gives you what a—I believe it's a 40-year exposure at air concentration that can be without causing adverse health effects in most people. This is obviously in adults and healthy working adults. It is a benchmark number you can look at and assess at some level." (Phillips Dep., Exhibit C to Plaintiffs' Brief, at 134-35.) That, in its unabridged form, is the testimony cited by plaintiffs as the supposed concession by Dr. Phillips that comparison to regulatory standards provides evidence of causation. But if that testimony is anything more than a general description of what a PEL is, it clearly is not the concession plaintiffs claim it to be. If anything, it is entirely consistent with Dr. McHugh's statement that if a person's exposure to a particular chemical is at a level less than some regulatory standard, including a PEL, it may safely be concluded that exposure to that chemical is not capable of causing adverse health effects in that person.

In sum, expert opinions that purport to show general causation by comparisons to regulatory standards are uniformly held inadmissible under Fed. R. Evid. 702. Courts recognize that regulatory standards do not designate thresholds of toxicity, and in fact are deliberately set far below levels believed to cause harm. Plaintiffs have cited no authority whatsoever to support Dr. Ryer-Powder's comparisons to such standards as grounds for her opinions in this case. Therefore, her opinions cannot stand.

B. Scientific Literature Does Not Support Dr. Ryer-Powder's Opinions.

As Textron explained in its initial brief, a central tenet of toxicology is that "the dose makes the poison." *Reference Guide on Toxicology* in *Federal Judicial Center Reference*

Manual on Scientific Evidence at 636 (3d ed. 2011). Hence an expert witness cannot establish that a plaintiff's exposure to a certain chemical was capable of causing his or her illness merely by citing studies in which far greater doses were shown to cause that illness. Not only must the expert explain why extrapolation from higher doses to lower doses is scientifically valid, he or she must also explain, if the studies involved animals, why extrapolation to humans from the particular species studied is likewise scientifically valid. *Id*. at 646, 661. Courts routinely exclude expert opinions that fail to demonstrate adequately the basis for either type of extrapolation. *See General Electric Co. v. Joiner*, 552 U.S. 136, 144 (1997); *Johnson v. Arkema, Inc.*, 685 F.3d 452, 463 (5th Cir. 2012); *Cunningham v. Masterwear, Inc.*, 2007 WL 1164832, at *7 (S.D. Ind. Apr. 19, 2007), *aff'd*, 569 F.3d 673 (7th Cir. 2009); *see also Reference Guide on Toxicology* at 661 n.77 (collecting cases in which expert opinions were excluded due to failure to explain scientific basis for extrapolating animal data to humans).

Plaintiffs claim that at least one of the studies relied on by Dr. Ryer-Powder did involve levels of exposure—albeit to rats—that are comparable to those here. According to plaintiffs, "[T]he Maltoni study (discussed in Dr. Ryer-Powder's Rebuttal, p. 7, Exhibit A) shows that exposure to vinyl chloride at a level only ten times greater caused more cancers. This study is directly comparable to the exposures at issue." (Plaintiffs' Brief at 6.) In the section of Dr. Ryer-Powder's rebuttal report cited by plaintiffs, she describes data presented in the Maltoni article (Exhibit J to Textron's initial brief) at page 16, Table 29. Dr. Ryer-Powder states:

> In a study performed by Maltoni and his colleagues (Maltoni et al., 1981), rats were exposed by ingestion of vinyl chloride in olive oil at doses of 0 (control, olive oil only), 0.03, 0.3, and 1 milligrams of vinyl chloride per kilogram of body weight per day (mg/kg-day). Animals were exposed daily, 4-5 days per week, for 59 weeks. At the control dose, there were 16 tumors per 100 animals, at the 0.03 mg/kg-day dose [the dose Dr. Ryer-Powder and plaintiffs claim to be ten times greater than the dose plaintiffs supposedly received—*see* Ryer-Powder Report, Exhibit A to Textron's initial brief, at 12], there were 18 tumors per 100 animals.

> At the 0.3 and 1 mg/kg-day doses, there were 13 and 24 tumors per 100 animals, respectively. This data demonstrates an increase in tumors at 0.03 mg/kg-day.

(Ryer-Powder Rebuttal Report, Exhibit A to Plaintiffs' Brief, at 6-7.)

What the foregoing data in fact shows is that there were *more* tumors at a zero dose and at a dose of 0.03 mg/kg-day than there were at a dose of 0.3 mg/kg-day. As a result, Maltoni said expressly that there was no observed correlation between the 0.03 mg/kg-day dose and the occurrence of tumors. (*See* Maltoni, *et al.*, at 21 ("None (or no increase) of the specifically VC related tumors shown in Table 71, observed in the seven basic experiments, was found at doses of 5 and 1 ppm (by inhalation) and 0.03 mg/kg-day (by ingestion).")) Maltoni also said that the lowest dose by ingestion at which a statistically significant correlation was observed between vinyl chloride exposure and tumor rate was 16.65 mg/kg-day. (*Id*. at 28, Table 70.) That is *5,500 times higher* than the dose to which plaintiffs were allegedly exposed.

Plaintiffs' assertion that the Maltoni study showed increased tumor rates caused by doses only ten times higher than the doses plaintiffs received—an assertion repeated *four times* in Dr. Ryer-Powder's rebuttal report (*see id*. at 2, 6, 7, and 9) is a jaw-dropping misrepresentation. Among the many conclusions that may be drawn from plaintiffs' and Dr. Ryer-Powder's astonishing lack of candor, one at the least is that Dr. Ryer-Powder's causation opinions are not supported by scientific studies involving levels of exposure comparable to plaintiffs'.

The Maltoni article and an article by Drew, *et al*. are the only articles cited by Dr. Ryer-Powder that reported studies conducted by the authors. All of the other publications she cited were "secondary literature"—articles or reports that "merely recite the results found in other studies or secondary literature" and that "are simply not scientific evidence." *LeBlanc v. Chevron USA, Inc*., 396 Fed. Appx. 94, 100 & n.7 (5th Cir. 2010). The Maltoni and Drew studies involved only rodents. Dr. Ryer-Powder made no attempt, in either her initial or rebuttal

report, to provide a scientific justification for extrapolating the results of those studies to humans. (Maltoni, in fact, expressly disclaimed any attempt to extrapolate the results of his studies to humans. *See* Maltoni *et al*. at 24, 26.) Nonetheless, plaintiffs claim that "[e]xtrapolation from the animal studies cited by Dr. Ryer-Powder is further supported because the species identified are commonly accepted for evaluating human risk." (Plaintiffs' Brief at 8.)

Besides the fact that plaintiffs offer no support whatsoever for that statement, it does not come close to providing the necessary scientific justification for extrapolating animal data to humans. As the *Reference Guide on Toxicology* explains:

> The expert should review similarities and differences between the animal species in which the compound has been tested and humans. This analysis should form the basis of the expert's opinion regarding whether extrapolation from animals to humans is warranted. The failure to review similarities and differences in metabolism in performing cross-species extrapolation has led to the exclusion of opinions based on animal data.

Reference Guide on Toxicology at 661 & n.77. Dr. Ryer-Powder did none of that.[1]

The only articles cited by Dr. Ryer-Powder that involved vinyl chloride exposure to humans were "secondary literature" rather than "scientific evidence," and therefore provide insufficient support for her opinions for that reason alone. Moreover, the levels of exposure noted in those articles were thousands of times higher than the levels to which plaintiffs were supposedly exposed, and Dr. Ryer-Powder made no attempt in her initial report to explain why extrapolation from those doses to the low doses here is scientifically valid. In her rebuttal report, however, Dr. Ryer-Powder states for the first time that, "While not at the same concentration of

[1] Plaintiffs claim that Dr. Phillips testified "that extrapolation from high dose animal studies is acceptable." (Plaintiffs' Brief at 7.) What Dr. Phillips actually said was, "It would depend on what the study is, what you are extrapolating." (Phillips Dep. at 221.) But the obvious point he was making, and that is established by case law in any event, is that there has to be some scientific basis for extrapolating from the facts of a particular study to the facts at hand, not that extrapolation from animal data to humans is always appropriate or can simply be assumed.

vinyl chloride as those studies, the increased vulnerability of children (especially infants and newborns) to toxic injury provides the scientific support to extrapolate to the current case." (Ryer-Powder Rebuttal Report at 6.)

Even if it were true that children are more susceptible than adults to adverse health effects from vinyl chloride (and Dr. Ryer-Powder cites no scientific evidence for that assertion), it would not mean that studies showing such effects in adults at levels many thousands of times higher than that to which a child was exposed establishes *ipso facto* that the child's level of exposure was capable of causing harm. The expert would still need to explain *how much more* susceptible a child is compared to an adult, and hence what high adult dose might correspond to a lower dose in children. Dr. Ryer-Powder makes no attempt to do that. Accordingly, her attempt at providing a scientific justification for extrapolating from high-dose studies noted in secondary literature (that do not provide adequate support for her opinions in any event) must be rejected.

Plaintiffs also maintain that because the high-dose occupational studies reported in the secondary literature cited by Dr. Ryer-Powder involved exposure by inhalation, and because more vinyl chloride is absorbed into the body by ingestion than by inhalation, it follows that the results of those studies support Dr. Ryer-Powder's causation opinions here. That contention was never made even by Dr. Ryer-Powder herself, but its defect is the same as the defect in her contention that children's increased susceptibility to harm from vinyl chloride is alone enough to make high-dose studies capable of showing causation here. Without any data about *how much more* vinyl chloride is absorbed by ingestion than by inhalation, it is impossible to know what high inhalation dose might correspond to a lower ingestion dose. The only occupational study reported in any of the literature cited by Dr. Ryer-Powder was in the article by Kielhorn, *et al.*

(Exhibit G to Textron's initial brief). It reported inhalation exposures 200,000 times higher than the doses plaintiffs allegedly received. There is absolutely no scientific basis on which to conclude that because those massive doses produced adverse health effects, the minute doses plaintiffs allegedly received are capable of doing the same.

Plaintiffs argue next that the ATSDR's report on the Myrtle Grove Trailer Park (Exhibit L to Textron's initial brief) "does nothing to call into question Dr. Ryer-Powder's *methodology*." (Plaintiffs' Brief at 10; emphasis in original.) That is so, plaintiffs say, because the report does not prove that levels of vinyl chloride comparable to the levels in this case do not cause adverse health effects. That in turn is true, they say, because the report involved a single case study with no control group and no medical examinations of subjects.

Plaintiffs' argument misses completely the point Textron was making in its initial brief about the Myrtle Grove report. Textron did not claim that because the ATSDR concluded that Myrtle Grove residents were not at risk for any adverse health effects, it proves plaintiffs are not at risk either. Instead Textron's point was that the ATSDR report confirms that there is no scientific literature showing adverse health effects in humans from exposure to vinyl chloride at levels even remotely comparable to those here. The ATSDR report says that expressly:

> There are no drinking water studies of vinyl chloride exposure in humans (ATSDR 1997). However, the scientific literature contains no evidence of a strong relationship between nonoccupational, environmental exposure to vinyl chloride and angiosarcoma of the liver or any other cancer (Zocchetti 2001, Ward et al. 2001). In particular, there is no evidence that vinyl chloride in drinking water, at doses that are achievable outside the laboratory, can cause cancer in humans via the oral route.

(ATSDR Report at 35.) Dr. Ryer-Powder purports to rely on scientific literature as part of the basis for her opinions in this case. The ATSDR's confirmation that there is no scientific literature showing adverse effects in humans from exposure to vinyl chloride at levels remotely

comparable to those here clearly does "call into question" her methodology. In fact, it utterly discredits it.

Finally, plaintiffs maintain that if the court finds that scientific literature does not support Dr. Ryer-Powder's opinions, it does not necessarily mean her opinions are inadmissible. They say case law establishes that support in scientific literature is not an absolute requirement for admissibility of expert opinions, especially for propositions that " 'are too particular, too new, or of too limited interest to be published.' " (Plaintiffs' Brief at 11, quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593 (1993).)

But apart from the fact that there is nothing about the possible health effects of vinyl chloride that is too particular, too new, or of too limited interest to be published, the only basis for Dr. Ryer-Powder's general-causation opinions in this case besides purported support in scientific literature is her comparison of alleged levels here to various regulatory standards. And as explained previously, cases are unanimous that medical experts' general-causation opinions that are based on exceedance of regulatory standards are inadmissible. So the absence of support in scientific literature leaves Dr. Ryer-Powder's opinions with no support at all besides her own say-so. That is the hallmark of inadmissibility under *Daubert*.

C. Dr. Ryer-Powder's Opinions and Calculations Fail to Account for the Effects of the Home's Water-Filtration System.

Testimony from plaintiffs' parents established that a whole-house water-filtration system was present in their home during the entire time plaintiffs lived there. (Jason Wood Dep., Exhibit C to Textron's initial brief, at 22, 27.) That testimony also established that the system's granular activated carbon ("GAC") filter—the component designed specifically to remove volatile organic compounds like vinyl chloride—was replaced once, at almost the exact time of E.W.'s adoption. (*Id.* at 44.) Testing by Textron's expert, Geoffrey Glanders, established that

the GAC filter left behind when the Woods vacated their home still removed roughly one-third of the vinyl chloride present in the home's untreated well water, even after having been used by the Wood family for a year and a half. (June 15, 2012 Expert Report of Geoffrey Glanders, Exhibit D to Textron's initial brief, at 36.) Mr. Glanders' testing also established that a new GAC filter would have removed all detectable levels of vinyl chloride from the home's well water, with that 100% effectiveness gradually declining over time until reaching the 33% effectiveness level after a year and a half. (*Id.*)

Despite the foregoing evidence, Dr. Ryer-Powder did not account for the effects of the home's filtration system in arriving at her assumptions about the levels of vinyl chloride to which plaintiffs were exposed over the course of their residency in Rochester. In particular, she based her dosage calculations and her ultimate opinions about causation on a sample of unfiltered water taken by IDEM on November 18, 2008, two weeks after plaintiffs left the home. That sample showed a vinyl chloride concentration of 8.4 parts per billion. (Ryer-Powder Report at 12.)

Plaintiffs proclaim that "Textron fails to inform the Court that the samples collected by MACTEC and IDEM were collected *after* the water passed through the filtration system. Dr. Ryer-Powder, therefore, included the presence of the filter into her analysis." (Plaintiffs' Brief at 13; emphasis in original.) But once again plaintiffs have misstated the facts.

As Textron explained in its response to plaintiffs' motion to exclude Mr. Glanders' expert report ("Textron's Glanders Response Brief"), the sample collected by IDEM on November 18, 2008 and the sample collected by Textron's consultant, MACTEC, on November 6, 2008 both came from an outside spigot at plaintiffs' home. (Affidavit of Paul Stork, Exhibit E to Textron's Glanders Response Brief, at 2-3, ¶¶ 5, 10, 12.) Water distributed to the home's outside spigots

did not pass through the home's filtration system. (Glanders Report at Appendix C, page 8.) Only the sample collected by MACTEC on November 3, 2008 came from inside the home and had passed through the filtration system. (Textron's Glanders Response Brief at 20.) The concentration of vinyl chloride found in that sample, 5.00 parts per billion (Ryer-Powder Report at 9), was 40% lower than the 8.4 parts per billion found in IDEM's November 18, 2008 unfiltered sample—almost exactly the reduction found by Mr. Glanders when he tested that same filter in June 2012. Thus, not only did Dr. Ryer-Powder ignore the roughly 40% reduction in vinyl chloride concentration that the year-and-a-half-old GAC filter would have achieved, she also ignored the near-100% reduction that that same filter would have achieved when new.

Apparently aware of the false factual premise of their argument, plaintiffs implore that "[a]t most, Textron raises a factual debate regarding whether 8.4 ug/l is a representative water sample of C.W. and E.W.'s exposure to vinyl chloride. It is, therefore, left to the jury to decide the correctness of the facts." (Plaintiffs' Brief at 12.) But there is no factual debate that Dr. Ryer-Powder based her dosage calculations and causation opinions on an unfiltered sample. Evidence of that fact is uncontradicted. And even if that evidence were disputed, there is no factual debate that a new GAC filter would have removed a significant portion of any contamination for a significant period of time and that Dr. Ryer-Powder's analysis failed to account for that in any way.

As Judge Miller said in *Ramsey v. Consolidated Rail Corp.*, 111 F. Supp. 2d 1030 (N.D. Ind. 2001), "Many cases decided under *Daubert* have excluded opinion testimony from experts who ignored facts or considerations that must be considered under methods based on reliable principles." *Id.* at 1038. This is such a case. Dr. Ryer-Powder's failure to account for the

effects of the home's water-filtration system renders her opinions and all of the calculations that underlie them so misleading and unreliable that they must be excluded from evidence.

III. Conclusion.

For the foregoing reasons, the Court should grant Textron's motion to exclude the opinions and testimony of Dr. Ryer-Powder.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on November 29, 2012, a copy of the foregoing was filed electronically. Notice of this filing will be sent to the following counsel of record by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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